DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

March 25, 2015

Kettenbach GmbH & Co KG
Ms. Katja Simon
Regulatory Affairs Manager
Im Heerfeld 7
35713 Eschenburg Hessen
GERMANY

Re: K143104
Trade/Device Name: Visalys® Core, PL-Core, PL-Core-C, PL-Core-X
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth shade resin material
Regulatory Class: II
Product Code: EBF
Dated: February 10, 2015
Received: February 13, 2015

Dear Ms. Simon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for use

510(k) number (if known): K143104

Device Name: Visalys® Core, PL-Core, PL-Core-C, PL-Core-X

Indication for Use:
Visalys® Core, PL-Core, PL-Core-C, PL-Core-X are dual-curing core build-up materials which are intended to be used for different types of core build-ups and luting of root posts

Prescription Use ___X___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary

In accordance with the requirements of the Safe Medical Device Act, Kettenbach GmbH & Co KG herewith submits a Summary.

A. Name and address of manufacturer:

Kettenbach GmbH & Co KG
Im Heerfeld 7
35713 Eschenburg
Germany
Establishment Registration No.: 9681356
Owner/Operator Number: 9022134

Name, title and phone number of official correspondent:

Simon, Katja
Regulatory Affairs Manager
Im Heerfeld 7
35713 Eschenburg
Germany
Phone: + 49 277 4705 0
E-mail: katja.simon@kettenbach.de

Name, title and phone number of U.S. Agent (Contact):

Roggenbau, Wilfried
InterGest North America LLC.
400 Oser Ave., Suite 1650
Hauppauge, NY 11788
Phone: 631 5010500 ext
Fax: 631 5011060
Email: roggenbauw@intergestna.com

Date of preparation: March 24th, 2015

B. Device Identification: **Visalys® Core**

Device Trade Name:	Visalys® Core, PL-Core, PL-Core-C, PL-Core-X
Versions:	white, dentin, blue
Common Name:	Dual-curing core build-up material

Classification of the device:

Device Classification Name:	Material, Tooth Shade, Resin
Product Code:	EBF
Device Classification No.:	Part 872.3690
Panel:	Dental
Regulatory Status:	Class II

C. Predicate devices:

Device Trade Name:	LuxaCore Dual
Applicant:	DMG USA, Inc.
510(k) No.:	K012307

Device Trade Name:	MULTICORE FLOW
Applicant:	Ivoclar Vivadent, Inc.
510(k) No.:	K040795

Device Trade Name:	Rebilda DC
Applicant:	Voco, GmbH
510(k) No.:	K040795

D. Device Description:

The Visalys® Core / PL-Variants are all available in two delivery systems:
1:1 25ml automix catridge
1:1 5ml double syringe
The pastes should be mixed and dispensed directly from the 5-ml-double syringe with the corresponding mixing tips (MLT Ø 3.2 mm) or using an dispensing gun DS-24 2:1/1:1 for the 25-ml-cartridge with the corresponding mixing tips (MBT Ø 4.2 mm).

The Visalys® Core / PL-Core-Variants are available in four different variations:
Visalys® Core, PL-Core, PL-Core-C, and PL-Core-X

The Visalys® Core / PL-Core-Variants are available in the following shades:
White, Dentin, and Blue

Visalys® Core, developed by Kettenbach, is a dual-curing, fluoride-containing composite used for the fabrication of radiopaque core build-ups and core fillings. The automixing, two-component system is based on a multifunctional acryl composite.
BPA or BPA precursors are not used in the manufacturing process of this device.
Visalys® Core has a firm consistency with good flow behavior. It is compatible with common light and dual-curing adhesives available on the market (Active Connect Technology) and already achieves strength values as specified with self-curing. Curing can be controlled as required at any time using optional light-curing.

PL-Core-C, developed by Kettenbach, is a dual-curing, fluoride-containing composite used for the fabrication of radiopaque core build-ups and core fillings. The automixing, two-component system is based on a multifunctional acryl composite.
BPA or BPA precursors are not used in the manufacturing process of this device. PL-Core-C has a firm consistency with good flow behavior. It is compatible with common light and dual-curing adhesives available on the market (Active Connect Technology) and already achieves strength values as specified with self-curing. Curing can be controlled as required at any time using optional light-curing.

PL-Core-X, developed by Kettenbach, is a dual-curing, fluoride-containing composite used for the fabrication of radiopaque core build-ups and core fillings. The automixing, two-component system is based on a multifunctional acryl composite.
BPA or BPA precursors are not used in the manufacturing process of this device. PL-Core-X has a firm consistency with good flow behavior. It already achieves strength values as specified with self-curing, however curing can be controlled as required at any time using optional light-curing.

PL-Core, developed by Kettenbach, is a dual-curing, fluoride-containing composite used for the fabrication of radiopaque core build-ups and core fillings. The automixing, two-component system is based on a multifunctional acryl composite.
BPA or BPA precursors are not used in the manufacturing process of this device. PL-Core has a firm consistency with good flow behavior. It already achieves strength values as specified with self-curing, however curing can be controlled as required at any time using optional light-curing

Differences between the variants:

1. Visalys® Core and PL-Core C are compatible with all common light and dual-curing adhesives available on the market
2. PL-Core and PL-Core X can be applied with bondings for which the use with dual-curing composites is recommended
3. Radiopacity is available in 2.5mm Al (Visalys® Core and PL-Core-X) or 2.0mm Al (PL-Core-C and PL-Core)

E. Indications for Use:

Visalys® Core, PL-Core, PL-Core-C, PL-Core-X are dual-curing core build-up materials which are intended to be used for different types of core build-ups and luting of root posts

F. Comparison of technological characteristic with the predicate devices

Product	Visalys® Core	Luxacore Dual	Multicore Flow	Rebilda DC
Manufacturer	**Kettenbach GmbH**	**DMG GmbH**	**Ivoclar Vivadent AG**	**Voco GmbH**
Product description	Visalys® Core, developed by Kettenbach, is a dual-curing, fluoride-containing composite used for the fabrication of radiopaque core build-ups and core fillings. The automixing, two-component system is based on a multifunctional acryl composite. BPA or BPA precursors are not used in the manufacturing process of this device. Visalys® Core has a firm consistency with good flow behavior. It is compatible with common light and dual-curing adhesives available on the market (Active Connect Technology) and already achieves strength values as specified with self-curing. Curing can be controlled as required at any time using optional light-curing.	Luxacore-Dual is an automatic mixing, dual cure composite that has been specially developed for all types of core build-ups and build-up fillings. Radiopaque Luxacore-Dual stands out due to its high compressive strength, and it cuts like dentin. The curing time can be self-determined due to additional light curing. It is possible to apply Luxacore-Dual directly using the Intra-oral-Tip and Endo-Tip.	MultiCore Flow is a dual-curing, radiopaque composite containing fluoride fillers that demonstrates excellent mechanical properties for core build-ups. It cures chemically without the use of light. Light-curing is optional. MultiCore Flow is available in a double-barrel cartridge or a double-push syringe with automixing tips for fabricating core build-ups using matrices.	Rebilda DC is a dual-curing, highly radiopaque flowable composite with excellent mechanical properties fore core build-up. Rebilda DC is available in three different shades to cover a large range of indications: Blue to visualize the transition between material and tooth substance, especially in molar and pre-molar areas; dentin shade for high aesthetic de-mands, e.g. under full ceramic restorations or composite resto-rations with high translucency; white as a possibility to visualize preparation margins an simulta-neously meet aesthetic demands.
Indication	Different Types of core build-ups; Luting of root posts	All types of core build-up; Cementation of root-posts	Core build-up of vital and non-vital teeth; Adhesive cementation of glass fibre-reinforced endodontic posts	Adhesive Core build-up of vital and non-vital teeth; Luting of fibre-reinforced resin-posts
Storage temperature	4-24°C / 40-75°F	2-25°C / 36-77°F	2-8°C / 36-46°F	4-23°C

Product	Visalys® Core	Luxacore Dual	Multicore Flow	Rebilda DC
Manufacturer	**Kettenbach GmbH**	**DMG GmbH**	**Ivoclar Vivadent AG**	**Voco GmbH**
Available Shades	Dentin, White, Blue	A3, White, Blue	Medium, Light, White, Blue	Dentin, White, Blue
Application system	25 ml Sulzer 2K cartridge 5 ml Sulzer 2K syringe	25 ml Sulzer 2K cartridge 5 ml Sulzer 2K syringe	25 ml Sulzer 2K cartridge 5 ml Sulzer 2K syringe	25 ml Sulzer 2K cartridge 5 ml Sulzer 2K syringe
A comparison of parameters in respect to processing time/mechanical properties was performed. The results demonstrated the substantial equivalence to the predicate devices.				

Table 1: Visalys® Core product description and characteristics in comparison to common competitor products

The Visalys® Core / PL-Core-Variants dual-curing core built-up materials are considered substantially equivalent to LuxaCore Dual (K012307), MULTICORE FLOW (K040795), Rebilda DC (K060893). There is no significant difference in intended use or technology. Each version of the Visalys Core material is substantially equivalent to the above listed predicate devices.

Technological Characteristics Summary:
The technological characteristics of Visalys® Core / PL-Core-Variants dual-curing core built-up materials are substantially equivalent to the above listed predicate devices technological characteristics.
Visalys® Core / PL-Core-Variants and the predicate devices are dual-curing build-up materials.

G. Summary of Non-Clinical Performance Testing:

Analysis of mechanical properties have showed equivalence to listed predicate devices. Analysis of compatibility with other devices used for dental restorations have shown comparable results compared to other materials on the market. Biocompatibility tests have been performed to assure biological safety in accordance with the ISO 10993 family. Tests in respect to cytotoxicity (ISO 10993-5), mutagenicity (OECD 487), sensitization (ISO 10993-10) and a chemical analysis showed, that Visalys® Core/PL-Core-Variants dual curing core build-up material biocompatibility data is comparable to other materials on the market. Therefore no toxicological risks and resulting hazards for patients, users and third parties can be concluded.

Additionally bench testing was performed to allow an evaluation of the mechanical properties of Visalys® Core in comparison to already products. The evaluation covers:

- Working time (ASTM D 4473, section 4)
- Cure point (ASTM D 4473, section 4)
- Depth of cure (ISO 4049 section 7.10)
- Film thickness (ISO 4049 section 7.5)
- Volume shrinkage (ISO 17304)
- Water sorption (ISO 4049 section 7.12)
- Solubility (ISO 4049 section 7.12)
- Radio-opacity (ISO 4049 section 7.14)
- E-Modulus (ISO 4049 section 7.11)
- Flexural strength (ISO 4049 section 7.11)
- Compressive strength (ISO 9917-1, AnnexD)
- Diametral tensile strength (ADA Spec. 27 section 4.3.7)
- Shade consistency (ANSI ADA Spec. 80)
- Color stability (ISO 4049 and ANSI ADA Spec. 80)

Conclusion:

Kettenbach GmbH & Co KG believes that the Visalys Core / PL-Core-Variants dual curing core build-up materials are substantially equivalent to the currently legally marketed products. It does not introduce new indications for use, has similar technological characteristics and does not introduce new potential hazards or safety risks.